



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,683	03/28/2001	Ping Feng	PZ020P1C1	3074

22195 7590 09/09/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,683	FENG ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2,13,14,17-20 and 25-58 is/are pending in the application.
- 4a) Of the above claim(s) 2,13,14,17-20,27,30-34,39,42-48,51 and 54-58 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 25,26,28,29,35-38,40,41,49,50,52 and 53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 27, 30-34, 39, 42-48, 51, and 54-58 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original restriction requirement dated 17 June 2003 presented VIII Groups of separate and distinct inventions. Applicant has elected to prosecute the invention of Group III, original claims 11, 12, 16, and 23 drawn to polypeptides classified in class 530, subclass 350. Along with the restriction requirement for the VIII Groups was a restriction requirement for SEQ ID. The examiner has interpreted the elected sequence as SEQ ID NO: 466, the first named sequence in the claims. Because Applicant has not stated otherwise, the sequence election is considered an election without traverse.

The claims above are drawn to separate and distinct inventions, as they refer to heterologous polypeptides, polypeptides encoded by HNTBI57 cDNA contained in ATCC Deposit Number 209423, and to polypeptide sequences heterologous to SEQ ID. NO:83. There are no claims in the original restriction election directed to these separate and distinct inventions.

Furthermore, the original restriction requirement stated that a single sequence be chosen. Applicant has elected SEQ ID NO: 466. This does not include Gene 83 or ATCC Deposit Number HNTBI57. Gene 83 comprises a large number of sequences, including SEQ ID NO: 466. Gene 83, in its entirety, is not the same as SEQ ID NO: 466. In fact, in Table 1, ATCC No. 209423 as it relates to Gene 83 is SEQ ID NO: 93 encoding the amino acid sequence SEQ ID NO: 221. These are not the same as SEQ ID NO: 466, and therefore represent separate and

distinct inventions. Only claims directed to SEQ ID NO: 466 will be examined on the merits.

All other claims are withdrawn from consideration.

Accordingly, claims 2, 13, 14, 17-20, 27, 30-34, 39, 42-48, 51, and 54-58 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant argues that the restriction requirement between groups does not present a serious burden to the examiner. However, given the increasing size of databases to be searched and the different class distinctions, the restriction requirement is still deemed proper and therefore, made final.

Claims Rejections-35 USC 101

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, as set forth in MPEP 2106.

The examiner is using the following definitions in evaluating the claims for utility.

"*Specific*" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 25, 26, 28, 29, 35-38, 40, 41, 49, 50, 52, and 53 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed polypeptides are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any polypeptide. The specification states that the polypeptides may be useful to assay protein levels in a biological sample, detect proteins by *in vivo* imaging, treat diseases, or be used as molecular weight markers. In fact, the specification summarized modern biotechnology generally but never

connects the specifically elected sequence to any particular or specific utility. This wishlist desire for a utility for the claimed sequence falls short of a readily available utility.

Further, the claimed polypeptides are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, the protein could be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. The research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein compound(s) such that another non-asserted utility would be well established for the compounds.

Claims 25, 26, 28, 29, 35-38, 40, 41, 49, 50, 52, and 53 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims Rejections-35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-38, 40, 41, 49, 50, 52, and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER: Claim 35 recites a second polypeptide consisting of amino acid residues 1 to 190 of SEQ ID NO: 466. There is no support in the specification for this particular fragment as it relates to SEQ ID NO: 466. Pages 283-284 only recite generic fragment sizes, but do not teach 1-190. The only mention in the specification of SEQ ID NO: 466, besides the sequence listing at page 206, is at page 165 as part of a bigger sequence which makes up Gene 83.

Claims 49 and 50 recite “at least 30 contiguous amino acids” and “at least 50 contiguous amino acids” of SEQ ID NO: 466, respectively. There is no support in the specification of these fragments of SEQ ID NO: 466. Applicants must point to the page and line numbers for support to amendments to the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 40 is rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 is vague and indefinite as to what is meant therein by the limitation "acceptable carrier". This implies that the carrier be acceptable depending upon the intended use of the protein. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm,

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

**MARJORIE MORAN
PATENT EXAMINER**

September 5, 2003
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

Marjorie A. Moran